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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/849,484	05/22/97	LAFFEND	L CR-9715-B

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LINDA A FLOYD
EI DU PONT DE NEMOURS & COMPANY
LEGAL PATENTS
WILMINGTON DE 19898

EXAMINER	
BUGAISKY,G	

ART UNIT	PAPER NUMBER
1814	

DATE MAILED: 01/02/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 10/16/97.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-33 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-33 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1814.

The examiner has reviewed the restriction requirement and has rejoined all Groups. Claims 1-33 are currently under consideration.

It is noted that statements of availability have been submitted for the deposited cell lines recited in claims 22, 24 and 25.

Drawings

The drafting division no longer reviews figures prior to submission of formal drawings.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention,"

in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C.§101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. §101.

Claim 22 is rejected under 35 U.S.C. §101 as claiming the same invention as that of claim 3 of prior U.S. Patent No. 5,633,362. This is a double patenting rejection.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 and 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,686,276. Although the conflicting claims are not identical, they are not patentably distinct from each other because they differ in scope. The independent claims of the instant application are directed to a process for production of 1, 3, propane diol, whereas the claims of the patent are directed to the process with a substrate other than glycerol or dihydroxyacetone.

Claims 1-18 and 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-19,21, 25, 28 and 30 of copending Application No. 08/687,852. Although the conflicting claims are not identical, they are not patentably distinct from each other because they differ merely in scope. The independent claims of the instant application are directed to a process using microorganisms having a dehydratase gene, whereas those of the copending application are drawn solely to microorganisms transformed with a dehydratase gene.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 and 23-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,633,362. Although the conflicting claims are not identical, they are not patentably distinct from each other because they differ merely in scope and are drawn to genes on the same cosmid and transformed organisms containing genes of the cosmid.

Claim Rejections - 35 USC § 112

Claims 1-12,14-18 and 31-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of generating 1, 3, propane diol with microorganisms transformed with the *Klebsiella pneumoniae dhaB* gene, does not reasonably provide enablement for production of 1, 3 propane diol by any microorganisms transformed with any diol dehydratase gene from any other organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The instant application shows the production of 1, 3, propane diol from organisms transformed with the glycerol dehydratase gene of *Klebsiella pneumoniae*, but does not address how to purify or isolate any other dehydratase genes from any other organism. No teaching is given regarding sequence similarity either between *dhaB* genes of different organisms or between dehydratase genes in general. Furthermore, the specification fails to teach any other dehydratase that can be used to generate 1, 3, propane diol; the diol dehydrase of Tobimatsu *et al* , for example, catalyzes the conversion of 1, 2 diols to the corresponding aldehydes and is not known to produce 1, 3, propanediol. The specification does not teach how one may use such an enzyme in the claimed process. It is deemed that the scope of the claims is much broader than the enablement provided by the specification and that undue experimentation would be involved in obtaining other dehydratase genes with which to practice the claimed invention.

Claims 26-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed inventions recite specifically deposited cell lines (microorganisms).

Since the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. §112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public. It is noted that applicants have deposited the organism but there is no indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

(d) the deposit will be replaced if it should ever become inviable.

Claims 1, 2, 5, 6, 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1 and 2, Applicants are reminded that latent capability for expression carries no patentable weight. It is suggested that the claim be amended to active tense.

In claim 5, presumably "gylcerol" should be "glycerol".

It is confusing in claim six as to what genes the DNA fragment may contain. Does the fragment encode one of *dhaB1, dhaB2* . . . or must it contain *dhaB1-B3*?

In claim 12, line 2, presumably "cerevisiase" should be "cerevisiae".

Claim 14 is presently confusing. The recited limitation that the carbon substrate has at least a single carbon atom is no limitation, as a molecule lacking a single carbon atom is not a carbon substrate.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-10,13,19-21, 23 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Tong *et al.* (1992; Appl. Biochem. Biotech.), who teach expression of the *dha* regulon of *Klebsiella pneumoniae* in *E. Coli* using the cosmid pTC1. In addition to the glycerol dehydratase gene, the pTC1cosmid contains genes for glycerol dehydrogenase and dha kinase. In Figure 1, they show the kinetics of 1, 3 propanediol production.

Claims 1-3, 5-10, 18, 19 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniel *et al.* The reference is anticipatory because it provides transformed *E. coli* which express

the *Citrobacter freundii dha* regulon and produce active glycerol dehydratase. The presence of the recombinantly produced enzyme is assayed by measurement of 1,3-propanediol production.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Walborsky *et al.*, who synthesized 1,3 propanediol . The reference is anticipatory because a product claimed by process is unpatentable if it is the same as, or obvious from, that product which was previously known to be made by another method *(In re Thorpe*, 227 USPQ 964, CAFC 1985). 1,3 propanediol does not change its identity because it is produced by fermentation.

Claims 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinstock *et al.* The reference is anticipatory because it provides the expression in *S. cerevisiae* of the cloned homolog of HIS3 of *S. kluveri*; the enzyme encoded by the HIS3 gene is imidazoleglycerolphosphate hydratase (p 358, column 2, lines 1-7).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 7:30 AM to 4:00 PM on weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert A. Wax, can be reached at (703) 308-4216.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[robert.wax@uspto.gov]**.

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
GROUP 180

gcb

December 15, 1997